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Study using Biocartis' liquid biopsy BRAF assay shows new option for retreatment of melanoma patients

Study and editorial 'A second chance for success with BRAF and MEK inhibitors in Melanoma' published in renowned clinical journal The Lancet Oncology

Mechelen, Belgium, **9 March 2017 -** Biocartis Group NV ('Biocartis' or the 'Company'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication in the renowned clinical oncology journal The Lancet Oncology of an important study[1] by Prof. Dr. Bart Neyns from the University Hospital in Brussels (Belgium). In this study, advanced metastatic melanoma cancer patients that had become resistant to their BRAF-targeted treatment were successfully given a retreatment with that same therapy following a three months pause after resistance confirmation. This is an important finding that could lead to more routine use of retreatment, especially for patients where no effective standard treatment is available. Biocartis' liquid biopsy test, the Idylla™ ctBRAF Mutation Assay (RUO[2]), was used in this study for the monitoring of the mutational status.

It often happens that patients with advanced melanoma become resistant to their treatments after some time. As a result, some patients can be left without a direct alternative treatment. The close monitoring of cancer treatment effectiveness is therefore essential. Liquid biopsy tests operating on blood plasma with the aim to detect circulating tumor DNA in the blood stream, can be an easy and less invasive monitoring tool for these patients, as demonstrated in the recent clinical study[3] by Prof. Dr. Bart Neyns, Head of Medical Oncology at the University Hospital Brussels (Belgium).

The study, which was published in the renowned clinical journal The Lancet Oncology, included 25 patients with advanced BRAFV600-mutant melanoma[4] who had become resistant to their treatments[5]. Rechallenging these patients, who previously progressed on BRAF plus MEK inhibition and were off-therapy for at least 12 weeks, with the same combination therapy, showed to be potentially effective and as such represents a potential new treatment option for these patients. The Biocartis' Idylla™ ctBRAF Mutation Assay[6] was used to monitor the BRAFV600 mutations of the patients included in the study.

Prof. Dr. Bart Neyns, Head of Medical Oncology at the University Hospital Brussels (Belgium), reacted: "*This is an important finding, as these results show that we can restart treatment with reasonable chance of success in cases where we do not have an effective standard treatment.*"

Geert Maertens, Chief Scientific Officer of Biocartis, commented: "*The study of Prof. Neyns shows for the first time that interruption after progression can restore sensitivity to a targeted therapy. In the study, Biocartis' Idylla™ ctBRAF Mutation Assay[2] has been instrumental in identifying patients benefiting from such retreatment. This clearly demonstrates the potential of our liquid biopsy test for use in high precision patient management.*"

More info on the study can be found on the website of The Lancet Oncology.

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[1] Schreuer et al., 'Combination of dabrafenib plus trametinib for BRAF and MEK inhibitor pretreated patients with advanced BRAFV600-mutant melanoma: an open-label, single arm, dual-centre, phase 2 clinical trial', The Lancet Oncology 2017, published online 3 March 2017.
[2] Research Use Only, not for use in diagnostic procedures.
[3] Combi-Rechallenge: NCT02296996. The study was performed among 25 patients of 18 years and older with advanced BRAFV600-mutant melanoma.
[4] All patients were aged 18 years or older, with BRAFV600-mutant melanoma who had previously progressed on BRAF inhibitors (with or without MEK inhibitors) and were off-treatment for at least 12 weeks, were treated with dabrafenib 150 mg orally twice per day plus trametinib 2 mg orally once per day.
[5] It concerns treatments with dabrafenib and/or trametinib (Tafinlar™ and Mekinist™, both products marketed by Novartis).
[6] The Idylla™ ctBRAF Mutation Assay is a Research Use Only assay, not for use in diagnostic procedures.

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About liquid biopsy testing

Research over the last few years has shown that fragments of tumor DNA are shed into the blood from primary tumors or metastatic sites[7]. These circulating DNA fragments can be used for diagnostic purposes, such as providing molecular information for treatment selection, or for monitoring disease progression in patients undergoing treatment. According to J.P. Morgan, the global market of liquid biopsy tests is estimated to reach $20 billion by 2020.

About Biocartis

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis launched the Idylla™ platform in September 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers eight oncology tests and two infectious disease tests. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

[7] Diaz and Bardelli, Liquid Biopsies: Genotyping Circulating Tumor DNA. J clin Oncol (2014) 32: 579-586.